DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, New York 14202

m3912n

June 30, 2000

WARNING LETTER NYK 2000-82

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Shafer, Sr., Part Owner
Shafer's Farm
3448 Stone Rd.
Middleport, New York 14105

Dear Mr. Shafer:

On April 24, 27, and May 1, 2000, U.S. Food and Drug Administration investigators conducted an inspection at your dairy operation located in Middleport, New York. This inspection confirmed that in March 1999 and June 1999 you offered two animals for sale for food in violation of Sections 402 (a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused an animal drug to become adulterated within the meaning of Section 501(a)(5).

On or about March 12, 1999, you offered a cow identified with ear tag 777 for slaughter as human food. The cow was slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 0.18 parts per million (ppm) penicillin.

On or about June 24, 1999, you offered a cow identified with ear tag 535 for slaughter as human food. The cow was slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 0.57 parts per million (ppm) penicillin.

A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). The presence of this drug in the kidney tissues of these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Shafer's Farm
Middleport, New York 14105

Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You also caused the drug Penicillin G Procaine, containing penicillin, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the labeling. Your use of this drug without following the labeled withdrawal periods causes the drug to be unsafe for use.

You should not consider this to be an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse which subsequently sold the meat to a processor that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Richard T. Trainor, Compliance Officer, at the following address: FDA, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely,

Brenda J. Holman
District Director